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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/563,637	06/12/2006	Christopher Milton Mathew Franco	19460	4137

23389 7590 06/07/2011

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GARDEN CITY, NY 11530

EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
06/07/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/563,637	FRANCO ET AL.
	Examiner	Art Unit
	ANISH GUPTA	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 March 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,39 and 46-48* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36, 39, 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed, 3/29/2011 is acknowledged. Claim 36 was amended and claims 1-35, 37-38, 40-45 have been canceled. Claims 36, 39, 46-48 are pending in this application.

Information Disclosure Statement

2. In the IDS filed March 20, 2009, Applicants cited the reference of "Coom, J.T." entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." The date Applicants provided was 2004. However, it is unclear if the date of this reference is actually 2004. First, the date of the publication never Appears on the reference it self. The only date present is the "Approved by the FHDC" date which is 2001. More importantly, Applicants have indicated in Journal articles that the date is not 2004, but is actually 2002. For example in Journal Plasmid, Applicant Journal Article entitled "Complete sequencing and analysis of pEN2701, a novel 13-kb plasmid from an endophytic Stretomyces sp.," Applicants cited the PHD thesis of Coombs. This too was entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." The date of this publication however was indicated as 2002. Furthermore, a search on the Flinder University Library system yielded a result for a PHD thesis entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." Again this is the same title as Applicants thesis. This was indicated as being published on 2001. Note that the Thesis submitted by Applicants indicates Flinders University. Applicants are requested to clarify the date of the publication submitted. Absent evidence to the contrary the thesis was publically available on 2001 (using the Flinder Library date) and this date has been utilized for this reference for prior art purposes.

Withdrawn Rejections

3. The rejection of claims 36, 39 and 46-48, rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is hereby withdrawn in light of Applicants amendments.

4. The rejection of claims 36, 48, rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is hereby withdrawn in light of Applicants arguments.

Maintained Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic,

without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

For written description, the analysis (a) considers actual reduction to practice, (b) disclosure of drawing or structural chemical formulas, (c) sufficient relevant identifying characteristics in the way of complete/partial structure or physical and/or chemical properties, functional characteristics when coupled with known or disclosed.

In the instant case, claims 38 and 39 recite metabolites derived from the nucleic acid sequence and antibodies directed to the actiomycete or the metabolites. This recitation does not provide written description for the claimed invention.

(a) actual reduction to practice/(b) disclosure of drawing or structural chemical formulas:

The specification fails to provide any species that correspond to an antibody that binds endophytic actinomycete as claimed. The claim states that that the antibody is directed against the endophytic actinomycete of claim 36 or 46. Presumably, the antibody binds an antigen on the surface of the bacterial species. However, the specification does not define the antigen(s) on the

surface of the protein to which the antibody is directed against.

(c) sufficient relevant identifying characteristics in the way of complete/partial structure or physical and/or chemical properties, functional characteristics when coupled with known or disclosed:

> The specification states :
> "Antibodies may be utilised, inter alia, to screen for the subject actinomycetes or to function as an antagonistic agent to the functional activity of the subject actinomycetes. Antibodies may also be directed to metabolites produced by the novel actinomycetes hereinbefore defined. Such antibodies may be monoclonal or polyclonal and may be selected from naturally occurring antibodies or may be specifically raised. In the case of the latter, an antibody may be raised to the actinomycete in its active or attenuated form or it may be raised to an antigen or epitope isolated from said actinomycete. To the extent that an antigen or epitope is utilised, it may first require association with a carrier molecule. Alternatively, fragments of antibodies may be used such as Fab fragments. Furthermore, the present invention extends to recombinant and synthetic antibodies and antibody hybrids. A "synthetic antibody" is considered herein to include fragments and hybrids of antibodies"

This is the sole description provided in the specification with regards to the antibody. The specification never identifies the antigen(s) present on the surface of the bacterial species against which an antibody maybe raised. In fact, the specification never identifies a single antigen against which the antibody may be raised. The specification merely states that antibody may be raised to the actinomycete in its active or attenuated form or it may be raised to an antigen or epitope isolated from said actinomycete.

(d) Representative number of examples

The specification fails to provide a single example that would fall within the broad definition of the claimed invention antibodies. The specification provides a general definition of antibodies

without providing a single example of a specific antibody that was raised or a specific antigen present within the bacterial species against which an antibody may be raised. The specification simply fails to provide a representative number of species for the broad genus of antibodies. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Response to Arguments

Applicants argue that "those skilled in the art would readily make and envision antibodies directed [against] endophytic actinomycete."

Applicant arguments have been fully considered but have not been found persuasive.

As stated in the previous office action, the issue is whether Applicants provided ample written description to establish possession of an antibody raised against actinomycete. As stated in the previous office action, the description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention.

In the instant specification, an antibody may be raised against the actinomycete species. Note that the claim implies an antibody against the bacterial species alone and not any specific antigen isolated from the bacterial species. As such, the bacterial species must have an antigen on the surface to allow the antibody to bind. The instant specification, however, the specification does not provide any specific antigens present on the surface of the bacterial species which would bind to an antibody.

Applicants have argued that their claims are similar to a situation where the novel protein

has been isolated and actual production of the antibody would not be required against this protein. It is acknowledged that raising antibodies is routine in the art. However, such procedure is only routine, when the antigen has been specifically identified. In the scenario outlined by Applicant, the novel protein (antigen) provides for a specific structure which would allow one or ordinary skill in the art to produce an antibody. The level of skill and knowledge in the art of antibodies at the time of filing is such that production of antibodies against a well-characterized antigen is conventional. In Applicants situation, however, such proteins and/or antigens are never identified nor characterized. The specification merely states an antibody may be raised to the actinomycete in its active or attenuated form or it may be raised to an antigen or epitope isolated from said actinomycete." (See paragraph [0515]). This portion of specification never mentions proteins/antigens present on the surface of the bacterial species. The specification never describes any structural characteristics of the antigen on the surface of the bacterial species or any antigen obtained from said bacterial. Indeed, a review of the specification, including the drawings and original claims, as well as prior art, finds no evidence of a description of any antigen. Thus, the antibody is directed to an unknown (antibody against actinomycete) that is identified only by reference to another unknown (i.e. antigen/protein on the bacterial surface).

Applicants attention is directed to In re Alonso, 88 USPQ2d 1849 (Fed. Cir. 2008), where the Federal Circuit held that the disclosure of a single antibody was insufficient to satisfy the written description requirement for a claim drawn to a genus of antibodies. In Alonso, the claims were drawn to a genus of monoclonal antibodies targeting a patients tumor. The specification only described the preparation of a single monoclonal antibody produced by a hybridoma cell line, but the claim encompasses a much larger genus of molecules, namely monoclonal antibodies that bind to a neurofibrosarcoma. In upholding the written description rejection, the Court reasoned:

> "The specification of the '749 Application does not characterize the antigens to which the monoclonal antibodies must bind; it discloses only the molecular weight of the one antigen identified in Example 2. This is clearly insufficient.7 The specification teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies implicated by the method. While Alonso's claim is written as a method, the antibodies themselves are described in purely structural language – "a monoclonal antibody idiotypic to the neurofibrosarcoma of said human." This sparse description of antibody structure in the claim stands in stark contrast to the detailed method of making the antibodies found in the specification." Alonso at 1853.

Much like in Alonso, the instant specification does not characterize the antigens to which the antibodies must bind. The specification teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies. Similar to Alonso, the genus of the claimed antibody encompasses a much larger genus of molecules. Note that in Alonso the Court noted some "sparse description of the antibody" in the form of molecular weight and a single example. However, the instant application does not provide even this sparse description. Given the lack of characterization of the antigen, the claims lack written description

Rejection is maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 36 and 46-48 remain rejected under 35 U.S.C. 102(a) as being anticipated by Coombs et al. (Plasmid, Jan. 2003).

Note claims 46-47 have been added in this rejection due to the fact that the claims are drawn to an isolated endophytic actinomycete.

The reference teaches pEN2701 which reads on the sequence claim 36, SEQ ID NO 12 (see page 90). This anticipates the claimed invention.

Response to Arguments

Applicants argue that claims 36 and 48 do not recite SEQ ID NO:12. Accordingly, Applicants argue that the reference does not meet the limitation of the claim.

Applicants arguments have been fully considered but have not been found persuasive.

There seems to be a misinterpretation of the claims. The claims are not drawn to DNA per se but are drawn to "[a]n isolated endophytic actinomycete characterized by a nucleic acid sequence." Thus, so long as the prior art teaches the endophytic actinomycete, it meets the limitation of the claim.

The reference teaches the isolation of endophytic streptomycete (See ape 87). Specifically, the reference states that actinomycete endoflora of wheat, a streptomyces sp. related to *Streptomyces caviscabies* and *Streptomyces setonii* was identified (see page 86). The reference states that DNA was recovered from all of the endophytic Streptomyces sp. isolated form **South Australia** (see page 87). The instant specification states:

> "Plants from 9 fields from three major **wheat growing regions in South Australia** were sampled at 6-7 week intervals across the growing season. The sites sampled on the Eyre Peninsula were Tuckey, Lock, Yabmana and Yabmana*. Yabmana* was adopted as a sample site at the 11 week sampling when it was observed that the crop in this field was particularly vigorous. These sample sites were characterised by sandy alkaline soils and relatively low rainfall (Tuckey, rainfall=330 mm/year). The sites sampled in the South-East region were Bool Lagoon, Struan and Wolseley. These were characterised by cracking clay soils and higher rainfall. The sites sampled in the mid-North region were Avon and Wild Horse Plains. These were of a loamy earth type soil. Avon was chosen as a sample site as this soil has shown to be suppressive to Rhizoctonia root rot of wheat and Take-all (Ggt) (Roget et.

al, 1999). These plants were used for endophyte isolation using protocol." (See paragraph [0525]).

The instant specification states that the source of EN16 is *Streptomyces tritictum gen nov. sp. nov* (see example 3 in the specification). The specification also states that the closes "[t]he members of the new genus *Streptomyces triticum*, including variants, showed significant differences with the 2 type cultures that showed the closest match on the basis of their 16S rDNA gene sequences; These were Streptomyces caviscabies (ATCC 51928), Streptomyces setonii (ATCC 25497)." (See paragraph 0556]).

Note that the reference teaches the isolation for the endophytes from the same source as the instant specification, i.e. South Australian wheat plants. The reference also states that the *actinomycete endoflora* of wheat, a streptomyces sp. related to *Streptomyces caviscabies* and *Streptomyces setonii*. Finally, the reference teaches that the species is *Streptomyces triticum*, similar to claim 48. Since the source is the same as the prior art and the both the specification and the prior art recite as similar relationship with *Streptomyces caviscabies* and *Streptomyces setonii*, the claimed endophytic actinomycete would have to be the same as corresponding to the prior art.

With respect to SEQ ID NO 7, the prior art bacteria would contain the claimed sequence for at least a few reasons. First, the source of the sequence is the same source in both the prior art and the specification. Specifically, the specification teaches that endophytes from South Australia is the source of SEQ ID NO 7. Since the prior art discloses the same source, i.e. South Australian wheat plants, the endophytic actinomycete of the prior art would have to contain the claimed sequence. Furthermore, the reference teaches EN27. This sequence has the capability of hybridizing to SEQ ID NO 7.

For these reasons, the rejection is maintained.

7. Claims 36 and 46-48 remain rejected under 35 U.S.C. 102(b) as being anticipated by Coombs (Thesis, 2001) for the reasons set forth below.

The claims are drawn to isolated endophytic actinomycete.

The reference teaches all of the endophytic actinomycete claimed in the instant application. Specifically, the reference teaches the sequence corresponding to pEN27 which reads on the sequence claim 36, SEQ ID NO 12 (see page 195). The reference also states that endophytes were isolated form root tissue and wheat seeds (see page 75). The reference states that the DNA was extracted and sequenced (see page 78-79). The reference specifically states that isolate named EN007 was isolated from YCED/B (see page 87). The reference teaches that EN7 has a 93% match to GenBank ane EMBL databases (See page 90-91). It should be noted that this is the same result recited in the instant specification in Table 3 (page 118 of the instant specification). Also note that the table 2.5 taught in the reference on page 95 is identical to the table 2 disclosed on page 117 of the instant application. Thus, since the reference discloses endophytic actinomycetes from the same source having the same characteristics, the endophytic actinomycete taught in the reference anticipates the claimed invention.

Response to Arguments

Applicants argue that the information regarding the Coombs thesis was subject to a confidentiality agreement. Applicants state that the "Cooms thesis was subject to an embargo until December 2004, i.e. after the earliest filing date of the subject application." Applicants argue that academics and research students were only able to access the thesis by signing and acknowledging that they would not publish any part of the thesis. Applicants argue that "even assuming arguendo, that the thesis is publically available prior to the priority date of the present application, there is no evidence of record that the isolated endophytic actinomycete (EN16) characterized by SEQ ID NO:

7 itself was publically available. The reference to EN16 in the Cooms thesis, without more, could simply be arbitrary laboratory designation."

Applicants arguments have been fully considered but have not been found persuasive.

While Applicant has argued that Cooms thesis was subject to an embargo until December 2004, Applicants have not presented evidence of this embargo. Furthermore, Applicants have not provided any evidence that academics and research students were only able to access the thesis by signing and acknowledging that they would not publish any part of the thesis. Absent evidence, one cannot make conclusions regarding the availability of the thesis.

It should be noted that Applicants have argued that the thesis was not available till 2004. However, evidence would imply that the thesis was publically available prior to 2004. For example in the journal Plasmid, Applicant Journal Article entitled "Complete sequencing and analysis of pEN2701, a novel 13-kb plasmid from an endophytic Stretomyces sp.," (published 2003) Applicants cited the PHD thesis of Coombs. This too was entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." The date of this publication however was indicated as 2002. Furthermore, a search on the Flinder University Library system yielded a result for a PHD thesis entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." Again this is the same title as Applicants thesis. This was indicated as being published on 2001. Note that the Thesis submitted by Applicants indicates Flinders University. Absent evidence to the contrary the thesis was publically available on 2001 (using the Flinder Library date) and this date has been utilized for this reference for prior art purposes.

Applicants have cited In Re Bayer, 196, U.S.P.Q. 670 (C.C.P.A. 1978), to support the position that the thesis is not prior art under 35 U.S.C. 102. However, the situation in Bayer is

distinguishable from the instant application. In Bayer, the court implied that only three members of the graduate committee had access to the thesis. Bayer at 674. Furthermore, the Court stated that the thesis could have only been located by having been informed of its existence by the faculty member and not by means of the customary research aids available in the library. Bayer at 674. Unlike Bayer, Applicants arguments establish that the thesis was available to anyone interested. Applicants state "readers other than academics and research students of Flinders University were not permitted to read Coombs without signing and acknowledging that they would not publish any part thereof." This establishes that the thesis was available not only to "academics and research students" but also readers. These groups of individuals are well beyond the three members of the graduate committee cited in Bayer. Moreover, one could have obtained using customary research aids. As indicated in the previous office action, the thesis was listed within the library system and had a catalog number of 579.37 C775i. The thesis was cited in a journal article as early as 2003 in the journal Plasmid. The citation was entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." The date of this publication was indicated as 2002. Thus, using "customary research aids" one of ordinary skill in the art could have easily found Applicants thesis. Bayer, therefore, is distinguishable over the facts of the present case.

Applicants have argued that reference to EN16 in the Cooms thesis, without more, could simply be arbitrary laboratory designation. As stated repeatedly, the claims of the instant application are drawn to endophytic actinomycete. The reference clearly teaches endophytic actinomycete. Much like the instant application, the designations for endophytic actinomycete are the same EN numbers. Much like the instant specification, Chapter 2 of the thesis, teaches the same methodology for isolating endophytic actinomycetes. Paragraphs [536]-[543] are identical to pages 79-81 of the thesis. Table 11 demonstrates in-vitro antagonism of Gaeumannomyces graminis. This

table shows the same results as those outline in table 4.1 on page 140 of the thesis. These are merely some examples of the similarities between the instant application and the thesis. One would reasonably conclude that the EN designation corresponds to the same EN designation as disclosed in the instant specification. Applicants arguments that the designation "could simply be arbitrary laboratory designation" is merely speculative. Since the thesis teaches the same EN7 as taught in the instant application, the sequence within the endophytic actinomycete has to be the same.

The rejection is maintained.

New Grounds For Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 36, 39, 46-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite an "actinomycete characterized by a nucleitide sequence corresponding to . . ." The recitation of "characterized by" is unclear. The claims are drawn to a bacterial species. It is unclear if characterized by means that the bacterial species contains the nucleic acid sequences naturally, is a transfected sequence, or is related to the bacterial species. If the nucleic acid is found within the species, then Applicants are requested to use language that clearly indicates that the endophytic actinomycete contains SEQ ID NO 7.

Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claim 39 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

The determination that "undue experimentation" would have been needed to make and use the claimed invention is not a single, simple factual determination. Rather, it is a conclusion reached by weighing all the above noted factual considerations. In re Wands, 858 F.2d at 737, 8 USPQ2d at 1404. These factual considerations include scope or breadth of the claims, nature of the invention, state of the prior art, level of one of ordinary skill, level of predictability in the art, amount of direction provided by the inventor, the existence of working examples, the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

(a) scope or breadth of the claims

The claim is drawn to an antibody against endophytic actinomycete containing SEQ ID NO 7.

(b) nature of the invention

The specification states, regarding the antibody, that the "[a]ntibodies may be utilised, inter alia, to screen for the subject actinomycetes or to function as an antagonistic agent to the functional activity of the subject actinomycetes." Thus, based on the specification the sole use for the claimed antibodies is as a screening agent and an antagonist to the bacteria.

(c) state of the prior art and (d) level of predictability in the art

The state of the prior art is established by Coombs references (Microbiology Australia, Plasmid and the Coombs thesis). These references characterize the bacterial stain isolated from wheat in South Australia. However, none of the references describe the antigens and/or surface proteins present on the bacteria that specifically identify the bacterial itself or is responsible for its fungal activity. That is to say, one of ordinary skill in the art would not know which surface proteins on the endophytic actinomycete lead to its biological activity in that one could use these proteins to generate antagonist activity. Nor could one of ordinary skill in the art identify which proteins are unique to the claimed species of endophytic actinomycete such that binding an antibody to these proteins would clearly screen for the claimed endophytic actinomycete. Therefore, detemerming whether a given antibody will have screening activity and antagonist activity against endophytic actinomycete species would be highly unpredictable.

(e) amount of direction provided by the inventor and working examples

The specification states :

> "Antibodies may be utilised, inter alia, to screen for the subject actinomycetes or to function as an antagonistic agent to the functional activity of the subject actinomycetes. Antibodies may also be directed to metabolites produced by the novel actinomycetes hereinbefore defined. Such antibodies may be monoclonal or polyclonal and may be selected from naturally occurring antibodies or may be specifically raised. In the case of the latter, an antibody may be raised to the actinomycete in its active or attenuated form or it may be raised to an antigen or epitope isolated from said actinomycete. To the extent that an antigen or epitope is utilised, it may first require association with a carrier molecule. Alternatively, fragments of antibodies may be used such as Fab fragments. Furthermore, the present invention extends to recombinant and synthetic antibodies and antibody hybrids. A "synthetic antibody" is considered herein to include fragments and hybrids of antibodies"

This is the sole description provided in the specification with regards to the antibody. Note that the sole use outlined for the claimed antibody is that "screen for the subject actinomycetes or to function as an antagonistic agent to the functional activity of the subject actinomycetes." In order for the antibody to be utilized as a screening agent, the antibody must bind to a specific antigen that would clearly allow one to recognize that this antigen was unique to the claimed endophytic actinomycete. In order to for an antibody to be useful as an antagonist, the antibody must bind to a surface antigen that is responsible for the functional activity of the subject endophytic actinomycete. However, the originally filed disclosure never identifies these specific antigens or any antigens for that matter. The specification does not characterize the antigens to which the antibodies must bind. The specification teaches nothing about the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies. The specification never provides any examples of antibodies that are useful in screening for the subject actinomycetes or to function as an antagonistic agent to the functional activity of the subject actinomycetes. Based on the disclosure, one would not be able to identify which antigens are responsible for activity such that they could raise specific antibodies against them for the purposes of screen for the subject actinomycetes or to function as an antagonistic agent to the functional activity of the subject actinomycetes.

(f) quantity of experimentation needed to make or use the invention based on the content of the disclosure

Since the specification does not characterize any antigens to which the antibodies must bind and does not provide any teachings regarding the structure, epitope characterization, binding affinity, specificity, or pharmacological properties common to the large family of antibodies, one would be

burdened with undue experimentation to generate and use the antibodies. This is because in order to practice the claimed invention, one would be burdened with undue experimentation to characterize specific antigens on the bacteria was unique to the claimed endophytic actinomycete and that is responsible for the functional activity of the subject endophytic actinomycete. Once characterized, one would have to generate the antibodies and determine if the antibodies bound to the proper antigen so as to allow for screening for the subject actinomycetes or to function as an antagonistic agent to the functional activity of the subject actinomycetes. The amount of experimentation to use the claimed invention would be undue.

Thus, the claim is not enabled.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10. Claim 36 and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Coombs et al. (Microbiology Australia).

The claims are drawn to isolated endophytic actinomycete.

The reference teaches that "[e]ndopytic actinomycetes were isolated from wheat plants in three regions of South Australia over the course of the growing season in 1998." (see abstract on page A32). The reference states that 61 endophytic actinomycetes were isolated in pure culture. Fame analysis showed that endophytic microflora of wheat differs significantly from with the actinomycete community commonly found in soil. Three isolates were shown to significantly affect

the growth of wheat in glasshouse trial, two strongly enhanced root growth and the other was shown to be an inhibitor of root growth. The references states that antifungal pot trial indicated approximately 15% of the isolates significantly reduce take all disease symptoms in wheat.

The instant specification states "[p]lants from 9 fields from three major **wheat growing regions in South Australia** were sampled at 6-7 week intervals across the growing season." Note that the reference teaches the isolation for the endophytes from the same source as the instant specification, i.e. South Australian wheat plants. The specifiation also states that the endophytic actinomycete exhibitied antifungal activity (see example 6-8). Thus, the prior art endophytic actinomycete is from the same source, i.e. wheat from S. Australia, and has antifungal activity. Thus, one can reasonably conclude that the endophytic actinomycete are the same.

With respect to SEQ ID NO 7, the prior art bacteria would contain the claimed sequence for at least a few reasons. First, the source of the sequence is the same source in both the prior art and the specification. Specifically, the specification teaches that endophytes from South Australia is the source of SEQ ID NO 7. Since the prior art discloses the same source, i.e. South Australian wheat plants, the endophytic actinomycete of the prior art would have to contain the claimed sequence. Furthermore, the reference teaches EN27. This sequence has the capability of hybridizing to SEQ ID NO 7.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANISH GUPTA whose telephone number is (571)272-0965. The examiner can normally be reached on 5/4/9.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anish Gupta/
Primary Examiner, Art Unit 1654